K091302

510(k) Summary of Safety and Effectiveness

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Robert K. Larsen, Regulatory Director
Preparation Date: April 6, 2009

JUL 23 2009

Device Name:

Trade Name:	Ascent Prep Porcelain Primer
Common Name:	Porcelain conditioner
Product Classification:	Agent, Tooth Bonding, Resin (21 CFR 872.3200, Product Code: KLE)

Legally Marketed Predicate Devices for Substantial Equivalence:

- Porcelain Primer, Manufactured by J. Morita USA, Inc.
  510(k) Number: K061322
- Clearfil Ceramic Primer, Manufactured by Kuraray Medical, Inc.
  510(k) Number: K061906
- Ultradent Porcelain Etch, Manufactured by Ultradent Products, Inc.
  510(k) Number: K951582

Rationale for Substantial Equivalence:

The aforementioned device shares similarities for use with the predicate devices on appliances intended for placement in the oral environment by means of conditioning the surface of porcelain dental appliances preparatory to the adhesion to or placement of said porcelain to teeth, resin based tooth restorative materials, or other oral appliances. This device features similar indications for use and application methods to the predicate devices.

Description of Submitted Device:

The Ascent Prep Porcelain Primer is a clear, low viscosity liquid composition containing conditioners and demineralizers in a solvent carrier. The liquid is marketed in preloaded 3cc syringes, which are shrink-wrapped for safety and marked with batch information for manufacturing traceability. Exact information regarding the material's constituents is found in Part 6: Specifications

Intended Uses of the Ascent Custom Fluoride Tray System:

Ascent Prep Porcelain Primer is intended for application on any porcelain appliance meant for placement in the oral cavity. The device is applied directly to the porcelain material by means of a disposable applicator tip attached to the delivery syringe. The device composition is dispensed on the surface of the porcelain and spread to cover the desired surface with an ample coating of the composition. After the proscribed time, the carrier liquid is evaporated with a gentle air stream. The composition works to create an adhesion interface between the porcelain substance and resin-based adhesive materials commonly utilized in dentistry.

Technological Characteristics of Substantial Equivalence:

Both the submitted and predicate devices are composed of similar substances, with similar active constituents in similar concentrations. Both have similar indications for use. Both have similar methods of application. Both are used in conjunction with dental restorative and preventative procedures. See Part 7: Performance Data.

Performance Standards:

ISO 7405:1997. Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry - Test methods for dental materials

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Performance Data

See Part 7: Performance Data

Conclusion

The Ascent Prep Porcelain Primer is substantially equivalent to the aforementioned predicate device with regards to purpose of the device, general composition, methods of application, and indications for use without raising any new issues regarding safety and/or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert K. Larsen
Regulatory Director
CAO Group, Incorporated
4628 West Skyhawk Drive
West Jorden, Utah 84084

JUL 23 2009

Re: K091300
Trade/Device Name: Ascent Prep Porcelain Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: April 6, 2009
Received: May 6, 2009

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091300

Device Name: *Ascent Prep Porcelain Primer*

Indications For Use:

Ascent Prep Porcelain Primer is indicated for the conditioning of porcelain dental appliances prior to the placement or adhesion of said porcelain to tooth structures within the oral cavity, resin based tooth restorative materials, or to other porcelain oral appliances.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)

Peter Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091300